1633

PATENT
Attorney Docket No: 28967/35061A

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#7 chn 8-24-00

Applicants: Alitalo et al.

U.S. Serial No.: 09/427,657

Filed: 26 October 1999

For: Use of VEGF-C or VEGF-D Gene or Protein to Prevent Restenosis.

Group Art Unit: 1633

Examiner: G. M. Lee

CERTIFICATION UNDER 37 CFR 1.10

I hereby certify that this paper is being deposited with the United States Postal Service as first class mail postage prepaid, on **August 8, 2000**, in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

David A. Gass

ELECTION WITH TRAVERSE IN RESPONSE TO RESTRICTION REQUIREMENT

Assistant Commissioner for Patents
Washington, DC 20231

Dear Sir:

In correspondence dated May 10, 2000, the U.S. Patent and Trademark Office issued a restriction requirement in the above-identified patent application, and set a three month period for response. This response to the restriction requirement is being timely filed on August 8, 2000. Reconsideration of the restriction requirement is respectfully requested in light of the following remarks.

I. The restriction requirement was improper and should be withdrawn.

The Examiner has required restriction of the claims of the application for examination purposes, citing 35 U.S.C. §121 and alleging four (I-IV) distinct inventions. The Applicants traverse the restriction requirement.

A. The Patent Office's basis for dividing the claims of Group I from the claims of Group III and for dividing the claims of Group II from the claims of Group IV fails to satisfy the statutory requirements for restriction.

The Examiner states that the invention claimed in Group I and Group III are related as product and process of use. The claims of Group I are directed to methods of treating restenosis using a specified polynucleotide, and the claims of Group III relate to a medical device such as an intravascular stent or catheter that includes a specified polynucleotide, and that is useful to treat stenosis and prevent restenosis. According to M.P.E.P. 806.05(h), a product and process of using the product can be shown to be distinct inventions if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be practiced with another materially different process of using that product. The Examiner alleges that in the instant case, "the polynucleotide can be used as a probe" for *in vitro* hybridization. However, neither the claims of Group I nor those of Group III claim a product that is a polynucleotide. Instead, the claims of Group III are directed towards a **medical device** containing a specified polynucleotide to prevent restenosis, and the claims of Group I are drawn to methods of treating restenosis using a specified polynucleotide. The medical device of Group III (*e.g.*, stent or catheter) cannot be used as a hybridization probe as alleged by the Examiner. The Examiner has failed to identify any other uses for the **device** of Group III other than for the practice of the method of Group I. Thus, the Examiner has failed to show how the product of the claims of Group III and the process of use of the claims of Group I are distinct inventions.

Similar arguments can be made for the Examiner's reasoning for alleging that the claims of Group II and those of Group IV are distinct. The claims of Group II are drawn to a method of treating restenosis using a specified polypeptide (a process of use), whereas the claims of Group IV are drawn to a **medical device** with a specified polypeptide (a product). The Examiner states that in this case, "the polypeptide can be used to produce antibodies" *in vitro*. However, a polypeptide is not claimed in the claims of Group II or Group IV. Furthermore, the **medical device** of Group IV cannot be used as antigen for antibody production. Thus, the Examiner's reasoning for alleging restriction between Group II ans IV is flawed.

B. The Patent Office's basis for dividing the claims of Group I from the claims of Group IV and for dividing the claims of Group II from the claims of Group III fails to satisfy the statutory requirements for restriction.

The Examiner states that the inventions of Group I and Group IV are drawn to distinct products capable of separate use. However, Group I claims are directed to a method of treating restenosis and do not claim a product. Thus, the Examiner's sole argument for dividing the claims of Group I and Group IV is based on a factual misunderstanding of the claims.

The Examiner also states that the inventions of Group II and Group III are drawn to distinct products capable of separate use. The claims of Group II do not claim a product and instead claim a method of treating restenosis. Once again, the Examiner's reasoning for dividing the claims of Group II and Group III is factually incorrect. No valid basis for restriction has been alleged.

C. Arguments to traverse the division of the claims of Group I from the claims of Group II.

The claims of Group I are drawn to a method of treating restenosis using a specified polynucleotide, whereas the claims of Group II are directed to a method of treating restenosis using a specified polypeptide. These two groups of claims are related in that the polynucleotides recited in the claims of Group I encode

the polypeptides recited in the claims of Group II. At page 4 of its restriction requirement, the Patent Office alleges that one of the reasons for the restriction requirement is because "...the search required for any given Group is unique and not required for any other Group...". However, the Patent Office has classified both Group I and Group II in class 514. The similar classification indicates that the patentability searches that the Examiner will conduct for these groups are likely to be co-extensive, and thus weighs against division of these groups of claims. Likewise, thorough searching involving polynucleotides will entail evaluating art pertaining to encoded polypeptides, and *vice versa*. Efficiency dictates that Group I and II should be examined together.

D. Arguments to traverse the division of the claims of Group III from the claims of Group IV.

The claims of Group III are drawn to a medical device with specified polynucleotides, whereas the claims of Group IV are directed to a medical device with specified polypeptides. The Examiner's reasoning for concluding that the invention of Group III and the invention of Group IV are drawn to products capable of separate use is flawed. The Examiner's argument states that the invention of Group III is a polynucleotide and that the invention of Group IV is a polypeptide, and reasons that the polynucleotide and polypeptide are capable of separate use, such as use as a hybridization probe or use to produce antibodies. The claims are not directed to polynucleotides or polypeptides, rather, they are directed to **medical devices** that include the polynucleotide or polypeptide as an anti-restenosis agent. Such medical devices cannot be used as hybridization probes or antigens as alleged by the Examiner. The Patent Office has not alleged any valid alternative uses for the two types of medical devices. Thus, the sole basis for distinguishing Groups III and IV is erroneous.

Moreover, these groups of claims are related in that the specified polynucleotides recited in the claims of Group III encode the specified polypeptides of the claims of Group IV. Because of this inter-relationship, the patentability searches

conducted for examination of the claims of these Groups will overlap, arguing against the restriction imposed on the claims of these two Groups (see discussion in part C above). In addition, Groups III and IV each contain exactly the same claims 22-28, all of which are generic to both Groups. Efficiency and common sense dictate that Groups III and IV should be examined together.

E. The restriction requirement should be withdrawn because the Patent Office has not demonstrated that a serious burden will result if restriction is not required, and because withdrawal will conserve resources of the Patent and Trademark Office and the Applicants.

Assuming *arguendo* that the claims as grouped by the Patent Office are "independent" and "distinct," the restriction requirement is nonetheless improper, because the Patent Office has failed to demonstrate that "a serious burden" will result if restriction is not required. See M.P.E.P. §803. **No such burden has been alleged in the restriction requirement.**

The lack of any serious burden is evident from consideration of the nature of the invention. The products recited in Group III claims may be used in the methods recited in Group I claims. Similarly, the products recited in Group IV claims may be used in the methods recited in Group II claims. In addition, the polynucleotides recite in Group I and III are identical, the polypeptides recited in Group II and IV claims are identical, and the polynucleotides recited in Group I and III encode the polypeptides recited in Group II and IV. These interrelationships suggests that no serious burden will result from co-examination of all of these claims. Instead, the Examiner will undoubtedly search overlapping prior art whether examining Groups I, II, III, or IV. Due to the co-extensive search, no serious burden exists in examining all four groups of claims together.

In fact, removal of the restriction requirement will conserve the resources of the Patent and Trademark Office, by minimizing the number of similar searches performed by the Patent Office examiners. The relatedness of the claims, discussed in detail above, demonstrates that the searches required for the divided

groups will be similar. If the restriction requirement is maintained, the Patent and Trademark Office will be required to perform duplicative searches of the same prior art, increasing its overall workload burden. Withdrawal of the restriction requirement will lessen the burden on the Patent and Trademark Office that is caused by duplicative searches.

F. Summary

For all of the foregoing reasons, Applicants respectfully traverse the restriction requirement as applied to Groups I, II, III and IV, and request that these groups be examined simultaneously.

II. The Applicants elect claims 1-18, 21, and 29-30, with traverse.

The Applicants hereby elect Group I, which includes claims 1-18, 21, and 29-30, drawn to a method of treating restenosis with a polynucleotide encoding a vascular endothelial growth factor, with traverse.

Respectfully submitted,

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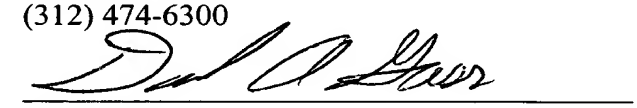
By: 

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Claim 0